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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,867	01/29/2004	Damon H. DeHart	ABB-126-A	4117

48980 7590 08/04/2011
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EXAMINER

NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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08/04/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@youngbasile.com
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Office Action Summary	Application No. 10/767,867	Applicant(s) DEHART, DAMON H.	
	Examiner TUAN NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/23/11.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,32-41,54,55,59,60,63,65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 32-41,54,55,59 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-10,63,65 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the reply filed on 5/23/11.

Response to Arguments

2. Applicant's arguments have been fully considered but they are not persuasive for the reasons set forth in detail below.
3. As to the rejection of independent claims 1 and 63, Applicants argue that Ehrlich (U.S. 2,801,633) in view of Humphrey (U.S. 5,607,401) fails to disclose the limitation of "first and second sharpened tips; and a body with a first end and a second end with a length in between, the body hollowed along a portion of its length, wherein first and second sharpened tips extend from the first end". Examiner respectfully disagrees.

Turning to the specification and drawings for guidance, one finds, page 11, lines 5-9, applicants discloses "unitary member 13 could be partially hollowed along its length (i.e., at first end 15 only) or solid along its entire length (and at least partially hollowed out in a subsequent boring, or drilling, process) without departing from the spirit of the present invention" and lines 14-15, "As noted briefly above, lancet 11 is formed by subjecting first end 15 of unitary member 13 to a series of grinding processes". Based on the disclosure above, one of ordinary skill in the art would understand that applicants fails to disclose the length of the hollowed body is beyond the gullet 27 or not (see Fig. 1(b)). In addition, in the last full paragraph at page 10, applicants disclose "Due to its uniform lateral cross-

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section, unitary member 13 can be mass produced by cutting an elongated, hollow cylindrical tube at equidistantly spaced intervals, which is highly desirable". Based on the disclosure above, one of ordinary skill in the art would understand that the hollowed body along a portion of the length of the lancet body is not a critical feature of the invention. Thus absent persuasive evidence, that the depth/length of the hollowed body is significant, the use of such is viewed as a matter of choice which a person of ordinary skill in the art would have found obvious.

In conclusion, the actual length of the hollowed portion is not clearly defined with respect to the distalmost end of the sharpened tips, thus, the limitation above has been given the broadest and reasonable interpretation. Examiner interprets the length of the sharpened tip, which includes a gullet, disclosed by the combination of Ehrlich/Humphrey as the hollowed portion.

4. As to the rejection of independent claim 3, applicants provide similar arguments as to the rejection of independent claims 1 and 63.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. **Claims 1-2, 63, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrlich (U.S. 2,801,633) in view of Humphrey (U.S. 5,607,401).**

Referring to **claims 1, 2, 63, 65 and 66**, Ehrlich discloses (Fig. 8) a unitary hollow lancet 23 having a first end (24) and a second end (opposite of 24), wherein the first end includes first and second sharpened tips 24s, the first and second sharpened tips spaced directly opposite each other and extending parallel to a longitudinal axis of the hollow lancet 23. Ehrlich discloses the lancet further include a portion for user to hold (Col. 6: 55-60) and the point is designed to give a length of 1 to 3 mm, which is the penetration depth that provide the most abundant capillaries (Col. 2:7-10 and Col. 3:10-15). Ehrlich also discloses providing a gauge for the depth of penetration of the point and providing stop elements limiting the depth of penetration of the point to the region of the most abundant blood supply beneath skin (Col. 2: 11-15). Ehrlich discloses the invention substantially as claimed except for disclosing the lancet is a seamless member. However, Humphrey discloses seamless hypodermic needle and lancet that are formed of

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polymeric material provide the advantage of the needle and lancet can be made in smaller diameter, resulting in less pain and less costly to manufacture (Col. 2: 35-36 and 49-51). Humphrey also discloses the geometry point of the needle and lancet can be either: flat, oblique, compound, double points or conical (Col. 6: 62-65 and Figs. 10-19). It would have been obvious to one of ordinary skill in the art to use the method of making the needle and lancet as taught by Humphrey to make the lancet as taught by Ehrlich in order to gain the advantage as taught by Humphrey. With respect to the limitation of "hollowed along a portion of its length". Note that the actual length of the hollowed portion is not clearly defined with respect to the distalmost end of the sharpened tips, thus, the limitation above has been given the broadest and reasonable interpretation. Examiner interprets the length of the sharpened tip, which includes a gullet, disclosed by the combination of Ehrlich/Humphrey as the hollowed portion. In addition, absent persuasive evidence, that the depth/length of the hollowed body is significant, the use of such is viewed as a matter of choice which a person of ordinary skill in the art would have found obvious.

8. With respect to the limitation of "first and second ground surfaces" in **claim 63**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by

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which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3. Figure 7 of Ayres' drawings (Ayres, U.S. 3,906,932) show the tip of the needle point is formed by grinding process.

Examiner contends that in the art of needle and lancet making using grinding process to make the tip geometry is old and well known in the art. It would have been obvious to use grinding process to produce the tip geometry as shown in Figure 7 as disclosed by Ayres to make the needle point as disclosed by Ehrlich because it has been held that using known manufacturing method to facilitate ease of manufacturing an article is old and well known in the art.

9. **Claims 3, 4, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrlich (U.S. 2,801,633) in view of Ayres (U.S. 3,906,932).**

Referring to **claims 3 and 4**, Ehrlich discloses (Fig. 8) a unitary hollow lancet 23 having a first end (24) and a second end (opposite of 24), wherein the first end includes first and second sharpened tips 24s, the first and second sharpened tips spaced directly opposite each other and extending parallel to a longitudinal axis of the hollow lancet 23. Ehrlich discloses the lancet having a portion for the user to hold (Col. 6: 55-60) and the point is designed to give a length of 1 to 3 mm, which is the penetration depth that provide the most abundant capillaries (Col. 2:7-10 and Col. 3:10-15). Ehrlich discloses the invention substantially as claimed except for disclosing the lancet is a seamless member.

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However, Ayres discloses using a unitary seamless cylindrical tube and grinding process to make a needle and needle point similar as taught by Ehrlich (Col. 2: 48-55 and Figs. 1, 3 & 7 and). It would have been obvious to one of ordinary skill in the art to incorporate the method of making a seamless body of the lancet and the point geometry as disclosed by Ayres to make the body and geometry point of lancet as disclosed by Ehrlich in order to gain the advantage of eliminating the rolling and stamping processes. Further, it would have been obvious to use grinding process to produce the tip geometry from a seamless tubular body as shown in Figure 7 as disclosed by Ayres to make the needle point as disclosed by Ehrlich because it has been held that using known manufacturing method to facilitate ease of manufacturing an article is old and well known in the art.

With respect to the limitation of "hollowed along only a portion of the length". Absent persuasive evidence, that the depth/length of the hollowed body is significant, the use of such is viewed as a matter of choice which a person of ordinary skill in the art would have found obvious.

With respect to the limitation of "first and second ground surfaces" in **claim 3**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA

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1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

With respect to the lancet is made from stainless steel. However, stainless less steel is old and well known in the art for exhibiting excellent mechanical strength, biocompatibility and super corrosion resistant. It would have been obvious to one of ordinary skill in the art to make the needle of Ehrlich/Ayres from stainless steel material so that it too would have the same advantage. Further, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the needle of Ehrlich/Ayres made from stainless steel, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

10. Referring to **claims 6-10**, Ayres discloses (Fig. 7) the first ground surface and second ground surface is a single angle ground surface and each of the ground surface extends from the horizontal plane at an acute angle relative to the longitudinal axis. Figure 7 shows the first and second surfaces mirror one another about the horizontal plane and each surface extends approximately 180 degrees about the longitudinal axis.

Examiner Requests for Interviewing

11. Because the application cannot be allowed in its present form, Examiner requests that the Applicant should call the Examiner at the telephone number given in the Conclusion section in order to provide an opportunity for coming to agreement upon allowable claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 571-272-4357. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TUAN NGUYEN/

Primary Examiner, Art Unit 3731